Instruction Sheet - Please Read Carefully

Instructions and Information Regarding Submission of Year 2000 Status Information for Compliant Products

Information is requested regarding the "Year 2000 Compliance Status" of vulnerable biomedical equipment (medical devices and scientific laboratory equipment) that has been determined by the manufacturer NOT to be affected by the Year 2000 or other date-related problems. Manufacturers are requested to provide a list of vulnerable products that have been determined to be Year 2000 compliant, including the data described below. This request is a special year 2000 data gathering request made pursuant to the Year 2000 Information and Readiness Disclosure Act.

Definition: For the purpose of this product status reporting, "Year 2000 Compliance" means, with respect to medical devices and scientific laboratory equipment, that the product accurately processes and stores date/time data (including, but not limited to calculating, comparing, displaying, recording and sequencing operations involving date/time data) during, from, into and between the twentieth and twenty-first centuries, and the years 1999 and 2000, including correct processing of leap year data.

This definition is compatible with the definition of Year 2000 Conformity contained in the British Standards Institute (BSI) published document PD2000-1:1998 and further described in BSI publication PD2000-4:1998. These publications may be obtained from the Internet at the web location http://www.bsi.org.uk/bsi/disc/year2000.html.

This definition is also the same as the definition of "Year 2000 Compliance" as used in the Federal Acquisition Regulations for information technology products (see 48 CFR Part 39.002) modified to address biomedical equipment. The intent is that for products to be Year 2000 compliant they must function as intended or expected, regardless of the date.

Applicability: A manufacturer's reporting of Year 2000 compliance status should include all products (units) produced which could still be in service. Submission of this data is a certification to the Government that the manufacturer has evaluated the products included in the submission and determined that the products are compliant.

Upgrades: In addition, the Y2K status information provided should reflect the condition of each model as originally marketed or with any manufacturer provided upgrade that the manufacturer can assure has been applied to all products of that model. The existence of a Y2K "fix" or upgrade does not render the product model compliant for the purposes of this status reporting, unless the manufacturer can assure that the upgrade has been applied to all products. Healthcare facilities need to know of the compliant or non-compliant status of the original or interim products to adequately assess their product inventories. Manufacturers should report products that were originally marketed in a non-compliant configuration or version as a "non-compliant" product, even if a compliant upgrade or version is now available, unless the manufacturer can assure that all such products have had the upgrade applied. The availability of the upgrade or compliant version should be described with the information provided in the report of a non-compliant product.

Clarification regarding date formats: There has been concern and possible confusion on whether a product can meet this definition of "Year 2000 Compliance" if it uses only two digits to describe the year, either in a display of the date or in a printed record of the date (or otherwise correctly uses the year or date information). It is the position of the FDA that this definition of a compliant product can be met by products that use only two digits to indicate the year in displays or printed records, provided the displayed year is correct before and after January 1, 2000. A product also can meet the definition of compliance if only two digits for representation of the year are used in internal device operations or in external data communication. Such use is compliant provided it does not result in incorrect functioning of the device,

such as incorrect sorting or information storage, or transmission of data which is incorrect or ambiguous when compared to the design specifications of the product and its data interface specifications. The format of any date information presented to the user by the device or available at any interface should be clear from the context of the usage or described in the product labeling.

Information requested: Manufacturers are requested to provide a list of compliant products including the following information for each compliant product:

1. *Manufacturer identification* - Information described for lines 1 through 3 on Form FDA 3474.

2. *Type of Product* - Identify the generic product type by providing the FDA Product Classification Regulation number under which the product is classified. This number will be used to associate the product classification name with the device for regulated products. The definitions for each product classification may be found in Title 21 of the Code of Federal Regulations in Sections 862 through 892 and on the FDA web site at http://www.fda.gov/cdrh/yr2000/classification.html. For products that have not been classified by the FDA, provide a description of the generic product type, not a manufacturer-specific trade or brand name. (This is line 5 on the Form FDA 3474.)

3. *Trade or Brand Name of Product* - Provide the name that is used by the manufacturer to identify the product (if any).

4. *Model Number(s)* - Provide the model number or model name that appears on the product.

5. *Original Manufacturer* - Name of the manufacturer under which this product was originally marketed if different from the reporting manufacturer.

6. *Serial Number(s)* - Provide serial number(s) where necessary to identify compliant products.

7. *Software Version Number(s)* - Provide software version number(s) where necessary to identify compliant products.

Product history: Manufacturers are asked to provide information related to any mergers, acquisitions or divestments of product or product lines which have resulted in a manufacturer that is different from the manufacturer identified on the product label. The purpose of this information is to aid users of these products in identifying the manufacturer(s) currently able to provide Y2K status information. Information provided will be incorporated in the corporate history data portion of the Federal Y2K Biomedical Equipment Clearinghouse. Information previously submitted does not need to be duplicated.

Submission of information: Information regarding compliant products may be submitted by mail, via the Internet or in electronic form using one of the means described in the attached "Options for Reporting Biomedical Equipment That Is Y2K Compliant."

Attachments: Listing of Product Classification Names
Forms for Reporting Compliant Product Data
Options for Reporting Biomedical Equipment That Is Y2K Compliant
Electronic File (E-File) Reporting Format Instructions